Cleveland Medical Devices Inc.™

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K970672

510(K) SUMMARY

MAY 22 1997

A) Submitter's Name: *Cleveland Medical Devices Inc.*

B) Address: 11000 Cedar Ave. Suite 439
Cleveland, Ohio 44106

C) Phone and Fax numbers: Phone: (216) 791-6720
Fax: (216) 791-6744

D) Contact Person: Robert N. Schmidt

E) Preparation Date: February 21, 1997

F) Classification Name: Electroencephalograph

Common / Usual Name: Electroencephalograph

Proprietary Name: Crystal-EEG™ Model 10

Classification: Class II The classification number for this device is 84GWQ and is reviewed by the Physical Medicine Panel.

Regulation: 882.1400
(a) An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.
(B) Classification. Class II (performance standards)

G) Substantial Equivalence: The design concept of the Crystal-EEG Model 10 is substantially equivalent in design to:

Hambrecht Associates Multi-Channel Electroencephalographic Telemetry System

H) Description: The Crystal-EEG Model 10 is a mobile, intermediate range, wireless, EEG system used for measuring and transmitting bioelectric signals such as electroencephalogram (EEG). It consists of a Transmitter; a Receiver Assembly which consists of the receiver, receiver cable, and power supply; the Software; Patient Accessories consisting of EEG Electrodes, headband, battery, and battery connector; and a PC Operator Interface which consists of Operator Interface Software, Transmitter Set-up Cable, and a Personal Computer (optional).

I) **Intended Use:** The Crystal-EEG Model 10 is a mobile, intermediate range, wireless, EEG system intended to be used for measuring and transmitting bioelectric signals such as electroencephalogram (EEG). The system allows extended EEG monitoring without having the subject tethered with wires.

J) **Summary of Safety and Effectiveness of Crystal-EEG Model 10:**
The Summary of Safety and Effectiveness on Crystal-EEG Model 10 reflects data available and presented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

The Crystal-EEG Model 10 is similar in operation and function to Hambrecht Associates Multi-Channel Electroencephalographic Telemetry System

	Crystal-EEG Model 10	**Hambrecht Associates Multi-Channel Electroencephalographic Telemetry System**
1) Transmitter and Receiver Assembly	8 channel	4 channels
	Dynamic range of inputs is +/-300 μV	Dynamic range of inputs is 5-250 μV
	Radiofrequency 902-928 MHz	Radiofrequency 88-108 MHz
	Operating Range 10-20 feet	Operating Range 200 feet
2) Software	three modules	None
3) PC Operator Interface	Optional	None

K) **Bench Testing:** The noise amplitude of the various channels of three Crystal-EEG Model 10 Transmitters was evaluated by shorting the input channels of the transmitter units together. The transmitted signal (noise) at the receiver end was recorded. **Figure 1** shows the results for the 24 channels of transmitted data (8 channels/Transmitter). The RMS of the noise was in the order of 1 uVolt.

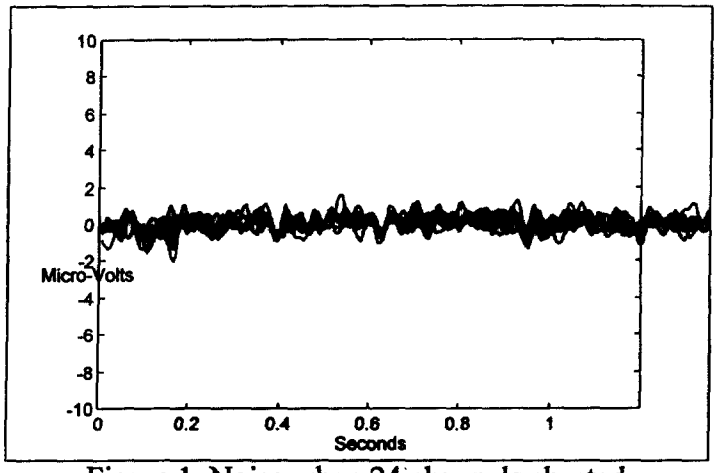

Figure 1. Noise when 24 channels shorted

The Crystal-EEG Model 10 unit was then evaluated in its ability to measure and transmit known analog waveforms. The analog signals were provided by a signal generator. **Figures 2** and **3** show two examples of such data from one typical channel with the analog sine waves at 5 and 20 Hz, respectively. For both cases the sine waves were measured and transmitted across the link.

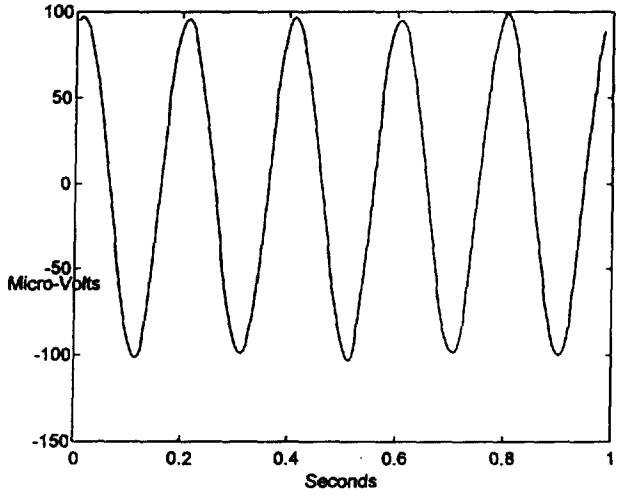

Figure 2. 5 Hz Sine Wave

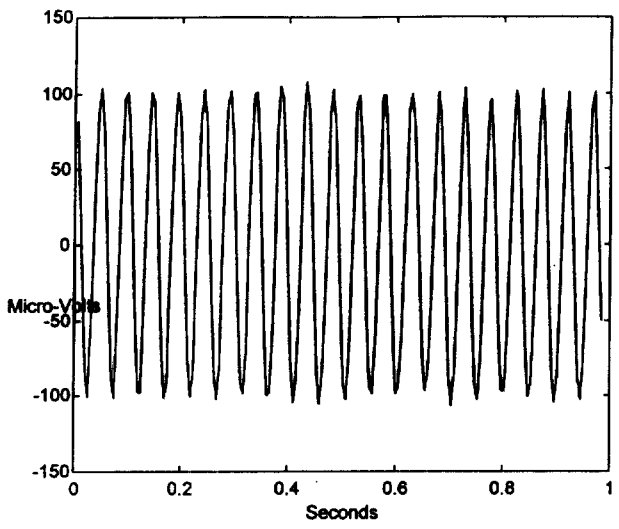

Figure 3. 20 Hz sine wave

The next step was to verify the functional accuracy of the low and high pass filters. The frequency of a sine wave was varied between 0.12 and 80 Hz and the peak values of the sine waves recorded. **Table 1** shows the measured peak value for each frequency. These data verify the accuracy of the implemented filters by showing expected levels of attenuation at the both ends of the spectrum.

Table 1. Frequency Response of the System to 100 uV Amplitude Sine Waves

Sine Wave Frequency (Hz.)	Peak Amplitude (uV)
0.12	12
0.2	22
0.4	45
0.7	69
1.0	83
2.0	95
5.0	97
10	98
20	100
30	72
40	18
50	6
60	5
80	3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1997

Mr. Robert N. Schmidt
Cleveland Medical Devices, Inc.
11000 Cedar Avenue, Suite 439
Cleveland, Ohio 44106

Re: K970672
Trade Name: Crystal-EEG™ Model 10
Regulatory Class: II
Product Code: 84GWQ
Dated: February 19, 1997
Received: February 24, 1997

Dear Mr. Schmidt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K970672

Device Name: Crystal-EEG™Model 10

Indications For Use: The Crystal-EEG Model 10 is a mobile, intermediate range, wireless EEG system intended to be used for measuring and transmitting electroencephalogram (EEG) signals.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K970672

Prescription Use X OR **Over-The-Counter Use**
(Per 21 CFR 801.109)